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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/254,288	04/02/1999	WOLFGANG TESCHNER	040433/0177	6758

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HELLER EHRMAN WHITE & MCAULIFFE LLP
1666 K STREET,NW
SUITE 300
WASHINGTON, DC 20006

EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 11/01/2002

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/254,288

Applicant(s)
Teschner et al.

Examiner
Irene Marx

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 10, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-18, 20-31, 33, and 34 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-18, 20-31, 33, and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/10/02 has been entered.

Claims 14-18, 20-31, 33, 34 are pending and are considered on the merits.

To conform with standard practice and for the sake of clarity, dependent claims should be amended to start with --The-- rather than "A".

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 14-18, 20-31, 33, 34 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14 and 31 are vague and indefinite and appear inconsistent in the recitation of the production of and of a product which is "citratated plasma" or "citrate-containing plasma" in the preamble, while the process in the body of the claim appears to be designed to result in a product wherein citrate is "exchanged" for mono or di-carboxylic acids and wherein the product is "substantially free of certain undesired metals". In this regard, the extent of the "exchange" is not claim designated and cannot be readily ascertained. Is it 1%, 10%, 80%, 100%? In other words, is it "total exchange"? Is the medicament citrate-free?

Also the recitation of "optionally" in claims 14 and 31 and claims dependent thereon with respect to the "exchange" of "citrate-bound metals" renders the claim vague and indefinite, since it is uncertain under which circumstances this option is or is not to be exercised.

Claim 14 is confusing regarding the recitation "said medicament does not take up any metals when stored in metal containing containers". It is unclear how this is assured. Also it is uncertain whether the metals not taken up are the undesirable metals mentioned, the metals in the storage containers or any metallic contaminants that may be present.

Claim 20 is confusing in the omission of a verb. Is "is performed" intended?

Claim 31 is vague and indefinite in that it is unclear whether the acids are intended to be water-soluble. Clarification is required. Also the product by process aspect of the invention is unclear in the recitation of "obtainable by". It is recommended that "obtained by" be replaced therefor to clarify the invention.

Claim 15 encompasses an improper Markush grouping because of the recitation of two "and" in the claim. Correct language is e.g. selected from the group consisting of A,B, **AND** C. The claim as drafted does not follow this form. See MPEP 2173.05(h)(a).

In claims 14 and 31 it is unclear what is intended by "non-precipitating conditions" in the present context.

Claim 16 is confusing in the recitation of "a salt of said monocarboxylate, dicarboxylate.". It is apparent that "monocarboxylate" or "dicarboxylate" pertains to a salt. Therefore the language appears redundant.

Claim Rejections - 35 USC § 102

Claims 14-17, 20-23, 26, 28, 31, 33, 34 remain rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 5561115 [A] for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant's arguments and the Teschner declaration filed 9/10/02 have been fully considered but they are not persuasive.

The declaration presents a comparative Example with the '115 patent. However, it is not clear how the parameters of the invention as claimed are applied to this example. The steps of the invention as claimed require "exchanging citrate and optionally citrate-bound metals in a plasma-protein containing solution for one selected from the group consisting of a water-soluble monocarboxylate, water-soluble dicarboxylate, a monocarboxylic acid and a dicarboxylic acid under non-precipitating conditions". This recitation includes, of course, sodium caprylate.

It is unclear in the Teschner declaration what is meant by "in the precipitating steps" regarding the comparative example (Item 7), since no particular section of the '115 patent is

cited. In addition, the statement in the Teschner declaration that the “citrate content is only reduced by ultradiafiltration against a caprylate containing diafiltration buffer to a value under the detection value” (Item 7) is not understood in the context of the present invention requiring steps “comprising” the “exchange” of citrate for an acid such as caprylate.

That salt, ethanol and metal ions are not reduced in the reference during diafiltration “to the extent according to the present invention” is not borne out by the active process steps of the invention **as claimed**.

With regard to the product as claim designated, it is noted that the product is merely “obtainable” by a certain process. This process is deemed to be disclosed by the reference.

As stated in *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977):

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product...Whether the rejection is based on “inherency” under 35 USC § 102 , on “*prima facie* obviousness” under 35 USC § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidence by the PTO’s inability to manufacture products or to obtain and compare prior art products.

Because the claimed and prior art products reasonably appear to be identical or substantially identical, or are produced by identical or substantially identical processes, the burden of persuasion is shifted to applicants “to prove that the prior art products do not necessarily or inherently possess the characteristics of [their] claimed product.”.

Therefore the rejection is deemed proper and it is adhered to.

Claims 14-16, 18, 20-23, 28, 29, 31, 33, 34 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 5372997 [B] for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant’s arguments and declaration have been fully considered but they are not deemed to be persuasive.

The distinction in the Teschner declaration between “removal” of citrate and “exchange” of citrate is not clear. While the principle of operation of the instant invention may be different, the process steps of the invention as claimed read on the reference. It is further unclear how arguments directed to “removal of citrate from the albumin solution to avoid leakage of aluminum from glass containers” relate to the claim designated invention. The alleged low yield in the reference is noted. However, the claimed process fails to stipulate specific process conditions. Therefore, any distinctions are not based on the invention as claimed.

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 103

Claims 14-18, 20-29, 31, 33 and 34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 5561115 [A] or US 5372997 [B] and US 5118794 [C].

Claims 14-18, 20-31, 33, 34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 5229498 [E] in combination with US 5372997 [B] for the reasons of record and the further reasons below.

The claims are directed to a process for reducing the concentration of metals in citrated plasma or a citrated plasma product comprising:
exchanging, particularly by filtration or a chromatographic method, the citrate anion for a mono- or di-carboxylic anion, particularly tartrate or caprylate anions, without precipitating the plasma proteins, recovering a plasma protein. A product of the process is also claimed.

Some of the claims require a virus inactivation step after removal of the citrate-bound metal.

The references are relied upon as explained in the last Office action.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants' arguments regarding the deficiencies of the primary references, '115 or '997, were rebutted above and are not repeated here.

With regard to the removal of citrate, applicants appear to argue total citrate exchange. Yet the extent of removal is unclear, particularly since the claims are drawn to the production of a "citrated plasma" or "citrate-containing plasma fraction".

With regard to claim 14 applicants argue that the limitation regarding "said medicament does not take up any metals when stored in metal containing containers" is a property of the medicament. However, it is uncertain how this is related to the specific process steps as claimed, which appear substantially similar to the prior art processes. It is unclear how this result is to be achieved. As noted *supra*, it is also uncertain whether the metals not taken up are the undesirable metals mentioned, the metal in the storage containers or any metallic contaminants that may be present.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

Applicants' might contemplate the insertion of specific process steps which are not taught in the references to better distinguish their process from the prior art.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



IRENE MARX
PRIMARY EXAMINER